DEPARTMENT OF HEALTH AND FAMILY SERVICES
WISCONSIN DIVISION OF PUBLIC HEALTH
P. O. BOX 2659
MADISON, WISCONSIN 53701-2659

PROGRAM FOR THE EVALUATION AND APPROVAL OF MARKETED SANITIZERS

Under the provisions of HFS 196, Appendix 7-204.11, Wisconsin Administrative Code, restaurant regulations, the Department may approve chemical sanitizing solutions and specify the concentration. Also, routine sanitization is required for all milk-contact surfaces encountered on farms and in our dairy processing plants. Because there are a variety of such agents, other than sodium or calcium hypochlorite, held forth and sold as sanitizing agents, it has become necessary to establish procedures whereby such chemicals can be analyzed and evaluated. Accordingly, arrangements have been made with the Wisconsin State Laboratory of Hygiene, Sanitizer Testing Program, 2601 Agriculture Drive, Madison, Wisconsin 53707, (608) 224-6268, or the National Sanitation Foundation Testing Laboratory, 789 Dixboro, P. O. Box 130140, Ann Arbor, Michigan 48113-0140, (734) 769-8010, to make efficacy tests for companies manufacturing or distributing sanitizers in Wisconsin, the cost of such test, original as well as retest, to be borne by such manufacturer or distributor. To have a product tested for approval by the Division of Public Health, the manufacturer or distributor must make financial arrangements with the indicated laboratories and then write the Division of Public Health, Environmental Sanitation Section, P. O. Box 2659, Madison, Wisconsin 53701-2659, giving the name of the product to be tested and the name and address of a jobber in Wisconsin where a sample may be procured.

The general procedures set forth by the Department on evaluation of sanitizers for all who intend to participate in this program are as follows:

I. *LABORATORY TESTING*

A) Germicidal and Detergent Sanitizers Test (current edition of AOAC)

1) Summary of Procedure:

The AOAC protocol provides for the testing of the sanitizer against Escherichia coli and/or Staphylococcus aureus using 30 and 60 second exposure periods and water having a hardness of 500 ppm synthetic hard water.

2) Standard of Effectiveness:

Results of the test, to be considered satisfactory, must show a 99.999% reduction in the number of viable organisms within 30 seconds in 500 ppm synthetic hard water. The challenge level of bacteria must be between 75-125 X 10^6 CFU/ml.

B) Available Chlorine Germicidal Equivalent Concentration Test (ACGECT) (current edition of the AOAC):

1) Summary of Procedure:

The test provides for a comparison ability of the sanitizer prepared in 500 ppm synthetic hard water to kill Staphylococcus aureus as compared to the ability of a standard sodium hypochlorite solution to kill the organism.

2) Standard of Effectiveness:

Results of the ACGECT, to be considered satisfactory, must show equivalent disinfecting activity to 100 ppm available chlorine. The germicide tested must show absence of growth in as many consecutive tubes of the subculture tube series as the 100 ppm available chlorine control solution.

C) Quality Assurance

1) Germicidal and Detergent Sanitizer Test

A positive and negative response must be demonstrated using a compound with known response characteristics. The compound used must pass at 500 ppm and fail at 900 ppm hardness when prepared according to manufacturer directions with 500 ppm and 900 ppm SHW. When testing quaternary compounds, the control must be a quaternary ammonia compound.

2) ACGECT

The test must show a response of at least one negative increment with 50 ppm NaOCl and at least one positive increment with 200 ppm NaOCl.

D) Requirements for Approval

Product must prove effective in one of the following three ways. The intent of this requirement is to provide testing of the sanitizer against both a gram positive and a gram negative organism.

1) The product must meet the standard of effectiveness using both E. coli and S. aureus in the Germicidal and Detergent Sanitizer Test, or

2) The product must meet the standard of effectiveness using E. coli in the Germicidal and Detergent Sanitizer Test and S. aureus in the ACGECT, or

3) The product must meet the standard of effectiveness using S. aureus in the Germicidal & Detergent Sanitizer Test, and S. typhi in the ACGECT.

II. *METHOD OF PRODUCT SUBMISSION*

Samples will be selected by authorized representatives of the Division of Public Health from unbroken containers in the hands of a Wisconsin jobber and forwarded directly to the laboratory, or products not on the market can be sent directly to the laboratory. The person submitting the product must advise the laboratory to forward copies of the test result to both the Division of Public Health and to the manufacturer or distributor or other person supplying the product. For products submitted directly to the laboratory, the Division of Public Health reserves the right to pick up a sample for testing when the product is marketed in Wisconsin.

Because of budget constraints in the Department of Health and Family Services for the operation of this program, please make arrangements for a free sample, preferably in the original container, for testing at the location you select for the Department staff to pick up a sample.

III. *TEST REQUIREMENTS*

A) Product Not Previously Tested for Which Approval is Requested:

If a chemical formulation has not been previously tested for approval, the product must be tested by either the Wisconsin State Laboratory of Hygiene or the National Sanitation Foundation Testing Laboratory.

B) Products Modified After Initial Test to Increase Effectiveness:

Products previously tested and approved under the Division's program and subsequently modified to increase their effectiveness must be retested for continued approval.

C) Products Modified After Initial Test by Reduction of Active Ingredients:

Products previously tested and approved under the Division's program and subsequently modified by reduction of the concentration of the sanitizer or decrease in the amount of wetting or sequestering agents are required to be retested.

D) Packaging for Another Concern:

If a wholesaler or compounder does the packaging for another concern and certifies that the material contained in the sanitizer marketed under a different name is identical with the original compound satisfactorily submitted, tested and approved, no further test will be required of the material marketed under the different name.

E) Approved Sanitizer Packaged by Other than the Original Compounder:

If a company packages a sanitizer which is certified as identical with an original compound submitted, tested and approved, testing of the product having a label different than the original approved sanitizer is required.

F) Periodic Retesting:

Periodic retesting of all sanitizers other than inorganic hypochlorites will be required approximately every 3 years. The retest must show effectiveness against both organisms. In the event the test fails to show such effectiveness, the following will apply:

1) The Division will immediately contact the manufacturer by letter or phone to determine:

a) Whether the manufacturer decides to authorize the laboratory to perform another test in which case the Division's representative will submit a second sample from an unbroken container directly to the laboratory performing the original retest.

b) Whether the manufacturer wishes to remove the sanitizer from the market in which case all parties concerned will be immediately notified of the deletion.

2) If the follow-up retest fails to show effectiveness against both organisms, the product will be removed from the approved marketed sanitizer list. All parties concerned will be immediately notified of the deletion.

IV. *PUBLICATION*

A) Notice to Manufacturer:

The manufacturer will be advised of approval or disapproval of the product submitted.

B) Publishing and Distribution of Approved List of Sanitizers:

The Division will publish a listing of approved sanitizers. Copies of the listing will be mailed to:

1) Health departments which act as agents of the Division under the restaurant program.

2) Members of the Interstate Milk Conference and Grade A Supervisory Agencies.

3) Environmental Sanitation Sanitarians and Milk Rating Officers, Division of Public Health.

4) All manufacturers and distributors participating in the program.

5) State Department of Agriculture, Trade and Consumer Protection.

V. *LABELING*

A) Registered and Approved:

The State Department of Agriculture, Trade and Consumer Protection requires that all sanitizers be registered and their labels be approved on an annual basis as of January 1 of each year.

B) Directions for Use in Eating Establishments:

All sanitizers shall have indicated on the product label the directions for sanitizing multi-use eating and drinking utensils. These directions shall be printed in a numbered outline form as follows (five steps):

1) Scrape and pre-wash utensils and glasses whenever possible.

2) Wash with a good detergent or compatible cleaner (a commercial cleaner or detergent can be recommended).

3) Rinse with clean water.

4) Sanitize in a solution of _____ ounces to _____ gallons of water (_____ ppm). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.

5) Place sanitized utensils on a rack or drainboard to air dry.

NOTE: A clean potable water rinse following sanitization is not permitted under HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 21 CFR 178.1010 (a)).

C) Requirements of the Wisconsin Conference on Interstate Milk Shipments:

The conference has no special labeling requirements at this time.

D) Approval Statement:

Manufacturers of approved products will be permitted to use the statement on their label that their product was "Approved under the regulations of the Wisconsin State Division of Public Health".